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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/974,870	10/12/2001	David Mark Whitcombe	1991-211	8792

6449 7590 03/26/2003

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EXAMINER

TUNG, JOYCE

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 03/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/994,870

Applicant(s)

Whitcombe et al.

Examiner

Joyce Tung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-22 and 24 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-22 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 10-22 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
 - a. Claims 10-22 and 24 are vague and indefinite because the phrase "the target nucleic acid" in claims 10-11 has no antecedent basis.
 - b. Claims 10-22 and 24 are vague and indefinite because of the phrase "a complementary sequence in an extension product of the primer corresponding to the target nucleic acid". It is unclear what is meant by "corresponding". It can not be determined whether the complementary sequence in the extension product of the primer is complementary to the target nucleic acid. Clarification is required.
 - c. Claim 12 is vague and indefinite because it is unclear whether the phrase "uncopied" means that the tail region is non-complementary to the template region. Clarification is required.
 - d. Claims 17 is vague and indefinite because of the language "releasably attached to the primer tail". It is unclear what is meant by the phrase "releasably attached". It can not be

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determined whether the integral signaling system is attached to the primer tail and then the integral signaling system is released. Clarification is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 10-12 and 14-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Whitcombe et al. (WO 97/42345).

Whitcombe et al. disclose a diagnostic primer having a non-complementary tail comprising tag and detector region (See the Abstract and pg. 2, lines 1-10). The non-complementary tail is non-complementary to any relevant genomic sequence or adjacent region (See pg. 3, lines 26-27). The length of the primer is less than 200 base pairs (See pg. 24). The detector region may be detected by the use of fluorescence resonance energy transfer or measuring a change in fluorescence polarization (See pg. 2, lines 27-31). A solid phase probe is to detect the immobilized primer extension products (See pg. 3, lines 1-3). The primer also comprises a restriction site on the middle position of the primer which may be cleaved releasing the detected fluorophore from its quencher (See pg. 15, lines 12-13).

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The claim language does not structurally specify the differences between the phrase "a template binding region", "target binding region" and "linker". The claim language also does not limit what is "a self-complementary stem duplex". In a nucleic acid sequence, complementary base pair region would satisfy the limitation of self-complementary stem duplex. Furthermore, the claim language does not limit what is the regions of internal hybridization that stabilize one or more component(s) of the signaling system in a given position. Thus, basis upon the analysis above, the teachings of Whitcombe et al. anticipate the limitations of claims 10-12 and 14-22.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 13 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitcombe et al. (WO 97/42345) as applied to claims 10-12 and 14-22 above, and further in view of Mullis et al. (4,800,159).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

The teachings of Whitcombe et al. are set forth in section 4 above.

Whitcombe et al. do not disclose that the primer has blocking moiety and the kit containing the primer.

Mullis et al. disclose that an oligonucleotide has blocking moiety which is deoxyribonucleotide or ribonucleotides (See column 6, lines 12-19). Mullis et al. also disclose a kit comprising primers (See column 3, lines 24-46).

One of ordinary skill in the art at the time of instant invention would have been motivated to make a primer comprising a blocking moiety and a kit comprising primers as taught by Mullis et al. because Mullis et al. address blocking moiety which is deoxyribonucleotide or ribonucleotides used in a primer or oligonucleotide and that the using of block moiety in the primer depends on the ultimate function or use of the oligonucleotide (See column 6, lines 12-19). Moreover, constructing a kit comprising primer for certain usage was well known and commonly practiced in the art for the convenience of performing a method. Thus, it would have been prima facie obvious for an ordinary skill in the art to make the kit comprising primers and constructing primer with blocking moiety in the tail.

Summary

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7. No claims are allowable.
8. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

9. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

JT
March 16, 2003

Jeffrey Siew
JEFFREY SIEW
PRIMARY EXAMINER
3/24/03